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**(54) MYOCARDIAL ISCHEMIA MONITOR**

GERÄT ZUR ÜBERWACHUNG VON ISCHÄMIE DES MYOKARDS

MONITEUR PERMETTANT DE DIAGNOSTIQUER L'ISCHEMIE DU MYOCARDE

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(56) References cited:  
EP-A- 0 209 804                      EP-A- 0 472 411  
DE-A- 2 816 494                      FR-A- 2 635 673  
FR-A- 2 645 005                      US-A- 4 562 846

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**EP 0 529 055 B1**

## Description

### BACKGROUND OF THE INVENTION

The present invention generally relates to an apparatus for assisting in the diagnosis of myocardial ischemia of a human heart. The present invention is more particularly directed to an apparatus for providing data related to the activity of the human heart, wherein the apparatus is fully implantable beneath the skin of a patient and wherein the data provided may be utilized to advantage for determining the presence or absence of ischemia in the human heart.

Patients who suffer what is commonly called a heart attack most often experience an episode of myocardial infarction. Myocardial infarction is a necrosis of cardiac tissue brought on by a reduction in blood flow to the infarcted area caused by either an obstruction in an artery or a thrombus in the artery. Patients who have suffered from myocardial infarction are generally treated with drugs or surgery to open the artery or undergo coronary artery bypass graft surgery to bypass the artery section having the obstruction or thrombus.

Each of the above-mentioned therapeutic techniques is effective in reestablishing blood flow through the effected artery. However, for each therapy, there is a percentage of patients that experience restenosis (reclosure of the artery) after therapy. Restenosis is largely an unpredictable event and the time required for the reclosure to occur may range from a matter of hours to years.

To monitor patients who have suffered from myocardial infarction, physicians may rely upon periodic ECGs (electrocardiograms) which generally require as many as ten leads to be attached to the patient. In addition, after the ECG, physicians then generally require the patient to take a stress test wherein the patient is caused to run on a tread mill until the patient is essentially exhausted to stress the heart. During and after the tread mill exercise the twelve lead is used to determine if the heart continues to receive adequate blood supply while under the stress conditions. Obviously such monitoring is inconvenient to the patient. Physicians may also rely upon Holter monitoring recordings which may last from 24 to 48 hours. These additional monitoring techniques are equally as inconvenient and in addition, are also annoying. Since all of these monitoring techniques can only be administered periodically at best as a practical matter, and because restenosis and thus future episodes of myocardial infarction are unpredictable events, all too often, a restenosis problem is not detected until the patient experiences pain or suffers an episode of myocardial infarction. Unfortunately, research has shown that pain is not a reliable indicator of ischemia.

EP-A-0 472 411, which is a document falling under Article 54(3) EPC, analyzes heart activity and if it determines that an abnormality is present, it automatically reports the same. It does not report specific data.

EP-A-0 209 804 simply transmits, on a real time basis, (no memory is involved) raw data consisting of electrograms, variations in transthoracic impedance, and pressure and pressure variations of a network. The foregoing are transmitted to an external device for evaluation.

FR-A-2 635 673 is not an implantable device.

From the foregoing, it can be seen that there is a need in the art for a new and improved monitor and method for monitoring patients who have suffered myocardial ischemia and thus may have a potential restenosis problem. The present invention provides such an apparatus because the apparatus is fully implantable beneath the skin of the patient and includes electrodes which are arranged to make electrical contact with the heart by, for example, being attached to or near the heart and to monitor heart activity in the form of an electrogram for each electrode. More particularly, the monitor of the present invention, monitors the electrogram from specific areas of the heart and more specifically, a predetermined electrogram parameter at each such area which has been shown to be reliable for indicating ischemia in the human heart. The apparatus is arranged to store only electrogram ST segment digital data for retrieval by the physician periodically and upon request by the physician through a command made by an external transmitter. As a result, the physician is provided with an early warning monitoring system of the state of the circulation in the patient's coronary arteries. As will be seen hereinafter, if the ischemia exceeds a predetermined limit, the apparatus provides the patient with a detectable alert signal informing the patient that the patient should consult his or her physician.

### Summary of the Invention

This invention relates to an apparatus as claimed in claim 1.

The present invention therefore provides an apparatus for assisting in the diagnosis of myocardial ischemia of a human heart. The apparatus is fully implantable beneath the skin of a patient and includes at least one electrode being implantable beneath the skin of a patient and arranged for establishing electrical contact with the heart. The apparatus further includes sensing means implantable beneath the skin of a patient and being coupled to the at least one electrode for generating an electrogram representative of the activity of the heart at the at least one electrode and wherein the electrogram includes ST segments having voltage magnitudes. The apparatus further includes read means implantable beneath the skin of a patient for reading the voltage magnitudes of the electrogram ST segments, memory means implantable beneath the skin of a patient and coupled to the read means for storing the voltage magnitudes of only the electrogram ST segments and communication means implantable beneath the skin of a patient and coupled to the memory means for transmitting the magnitudes of the elec-

trogram ST segments to a nonimplanted external receiver.

The apparatus may further include a microprocessor arranged to determine the difference between the sensed ST segment voltages and a base line voltage and to activate an alarm means when the absolute magnitude of one of the differences exceeds a commanded limit. The microprocessor may further be arranged to cause an ST segment voltage to be stored in the memory means only when the absolute magnitude of its corresponding difference exceeds a commanded limit.

### **BRIEF DESCRIPTION OF DRAWINGS**

The features of the present invention which are believed to be novel are set forth with particularity in the appended claims. The invention, together with further objects and advantages thereof, may best be understood by making reference to the following description taken in conjunction with the accompanying drawings, and the several figures of which like reference numerals identify identical elements, and wherein:

Figure 1 illustrates a representative electrogram of a healthy human heart;

Figure 2 illustrates a representative electrogram of a human heart suffering from ischemia; and

Figure 3 is a schematic block diagram of a fully implantable apparatus embodying the present invention for assisting in the diagnosis of myocardial ischemia of a human heart and which is shown in association with a human heart in need of monitoring for ischemia.

### **DESCRIPTION OF THE PREFERRED EMBODIMENT**

Referring now to Figure 1, it illustrates an electrogram 10 representative of the electrical activity of a healthy heart. As will be noted, the electrogram 10 includes a QRS complex 12 which is preceded by a base line 14 and which is followed by an ST segment 16. As will also be noted from the electrogram 10, the voltage magnitude (ST) of the ST segment 16 is approximately equal to the voltage magnitude (BL) of the base line section 14 in the healthy heart.

Referring now to Figure 2, it illustrates a representative electrogram 20 of a human heart suffering from ischemia. The electrogram 20 like the electrogram 10 includes a QRS complex 22 which is preceded by a base line 24 and which is followed by an ST segment 26. As can be noted from Figure 2, the magnitude (ST) of the ST segment voltage is greater than the magnitude (BL) of the voltage of the base line 24. The difference between the voltage of the base line 24 and the voltage of the ST segment 26 is referred to in the art as the ST segment voltage shift.

The ST segment voltage shift may be either in a positive or a negative direction depending upon the type of electrode used (bipolar or unipolar) and the position

of the electrode relative to the ischemic tissue. As indicated in Figure 2, the voltage shift is in the positive direction which will normally result with unipolar electrodes. Hence, human hearts suffering from ischemia may have either a negative or positive shift detected in the ST segment voltage. As a result, the absolute magnitude or value of the difference between the base line voltage and the voltage of the ST segment is considered to be a reliable indicator of potential ischemia in the human heart and, for example, a predetermined limit difference or shift of approximately five millivolts may be considered to indicate a condition of ischemia in the human heart. As will be seen hereinafter, the ischemia monitor of the present invention reads the voltage magnitude of the ST segment following the QRS complex.

Referring now to Figure 3, it illustrates an ischemia monitor 30 embodying the present invention shown in association with a schematically represented human heart 32 in need of monitoring for myocardial ischemia. The heart 32 illustrated in Figure 3 is shown to generally include a right atria 34, a right ventricle 36, a left atria 38, and a left ventricle 40. The right ventricle 36 and left ventricle 40 are shown in cross section to reveal myocardium regions 42 and 44 which may possibly suffer from ischemia.

The apparatus 30 generally includes a plurality of electrodes 50, 52, and 54, a sensing means 56, a read means 58, a memory 60, and communication means 62. All of the components of the apparatus 30 are contained within a common inclosure indicated by the dashed line 64 except for those portions of electrodes 50, 52, and 54 which extend outside of the common inclosure 64.

The electrodes 50, 52, and 54, as illustrated in Figure 3, are epicardial electrodes and are thus arranged to be attached to the outer surface of the heart 32 in the region of the myocardium 42 and 44. Preferably, if the location of the region of potential myocardial ischemia is known, it is preferred to place the electrodes 50, 52, and 54 over or near each myocardial infarction or ischemic region where restenosis is considered to be most likely to occur. Such regions would be, for example, where grafts were made during coronary artery bypass graft surgery, for example. The electrodes 50, 52, and 54 are unipolar electrodes having poles 66, 68, and 70 respectively. The poles 66, 68, and 70 are placed into electrical contact with the heart by either being placed directly on the heart or to tissue near the heart for picking up electrical activity such as electrical activations within the heart 32.

The sensing means 56 comprises a plurality of sense amplifiers 72, 74, 76, and 78 with sense amplifiers 72, 74, and 76 having inputs coupled to the electrodes 50, 52, and 54. Although three electrodes are illustrated in the figure, it is contemplated by the present invention that a fewer or greater number of electrodes may be utilized without departing from the present invention. As a result, an electrogram is generated for each of the electrodes with each electrogram independ-

ently representing the activity of the heart 32 at each respective electrode pole and hence at each respective region of the heart being monitored.

The read means 58 is preferably an analog to digital converter 80 which is coupled to the outputs of the sense amplifiers 72, 74, 76, and 78 one at a time by a multiplexer 82. The analog to digital converter 80 reads the electrocardiogram voltages relative to a reference voltage such as the voltage of enclosure 64 and converts the electrocardiogram voltages to multiple-bit words in parallel-bit format. The multiple-bit representations of the electrogram voltages are processed by a microprocessor 84.

As will be noted in Figure 3, the microprocessor 84 is coupled to a clock source 86 and to the multiplexer 82. The microprocessor is also coupled to the memory 60 by a multiple-bit address bus 88 and a bi-directional multiple-bit data bus 90. The address bus 88 permits the microprocessor 84 to address desired memory locations within the memory 60 for executing write or read operations. During a write operation, the microprocessor stores data in the memory 60 at the addresses defined by the multiple-bit addresses conveyed over bus 88 and conveys the data to the memory 60 over the multiple-bit bus 90. During a read operation, the microprocessor 84 obtains data from the memory 60 from the storage locations identified by the multiple-bit addresses provided over bus 88 and receives the data from the memory 60 over the bi-directional bus 90.

The microprocessor 84 controls the reading of the electrogram voltages and the storing of data, such as the magnitudes of the ST segment voltages, in the memory 60. By being coupled to the clock 86 and to the multiplexer 82, the microprocessor 84 is able to select which one of the inputs of the multiplexer is to be coupled to the input of the analog to digital converter 80 and to synchronously store the data in the memory 60. The microprocessor samples the electrogram voltages provided by the sense amplifiers 72, 74, and 76 as digitized by the analog to digital converter 80 at a rapid rate and detects when the slope of the electrogram is either a rapid positive or negative slope which may be seen in the electrograms of Figures 1 and 2. Following the detected rapid positive or negative slope in the electrogram, the microprocessor then looks to obtain the ST segment voltage from the analog to digital converter 80 from each of the sense amplifiers 72, 74, and 76. Preferably, the microprocessor obtains the ST segment voltage a predetermined time after the QRS complex 22 is detected by the detection of the rapid positive or negative slope in the electrogram. Such a predetermined time may be, for example, 80 ms.

As an alternative to the configuration illustrated in Figure 3, the inputs of multiplexer 82 may be coupled directly to the electrodes 50, 52, and 54 with the output of the multiplexer then being coupled to a single sense amplifier. This would have the benefit of lower power consumption and assuring the same amplifying gain being applied to each electrogram. However, this would

also result in slower voltage sampling due to voltage settling times.

The communication means 62 includes a receiver/transmitter 63 and a transmitting coil 65. Such communication means are well known in the art and may be utilized for receiving commands from external to the implantable enclosure 64 and for transmitting data to a receiver external to the implanted enclosure 64. One such communication system is disclosed, for example, in U.S. Patent No. 4,586,508. The receiver/transmitter is coupled to the microprocessor 84 for conveying commands to the microprocessor and for receiving data from the microprocessor which the microprocessor acquires from the memory 60.

The microprocessor in receiving commands from external to the implanted enclosure 64 may be provided with a predetermined voltage level of the patient, such as the base line voltage, by the physician. When the microprocessor identifies the ST segment voltage, it may then determine the difference between the ST segment voltage and the base line voltage. If the absolute magnitude of the resulting difference is greater than a predetermined limit which may also be provided from external to the enclosure 64 by the physician, the microprocessor then may cause either the ST segment voltage or the determined difference (ST segment shift) to be entered into the memory 60. Since not all measured data is entered, in this manner, memory space within memory 60 may be conserved for only ST segment readings which are considered important to the physician. Also, for the ST segment voltages or voltage differences entered into the memory 60, the microprocessor may time stamp each entry so that upon being read out by the physician, the physician will know when the significant events occurred.

The microprocessor may also be programmed to determine the base line voltage on its own. This may be accomplished by storing the base line voltages and then, after the detection of a QRS complex, accessing the memory for the base line voltage measured a second predetermined time before the QRS complex. Such a second predetermined time may be 80 ms. Once having determined the base line voltage and after having the corresponding ST segment voltage, the microprocessor can then calculate the absolute value of the ST segment voltage shift. As a further alternative, capacitive coupling may be utilized to force the base line voltage seen by the microprocessor to be zero volts.

For obtaining data from the implanted monitor 30, the physician requests the data from external to the enclosure 64. The command is detected by the receiver/transmitter 63 and then conveyed to the microprocessor. In response to receiving the external command, the microprocessor 84 addresses the memory 60 to obtain the data stored in the memory 60. The microprocessor then conveys the data to the receiver/transmitter 63 which then transmits the data to an external receiver for readout by the physician.

It will also be noted that in Figure 3, the apparatus

30 includes an alert means 100 which is coupled to the microprocessor 84. The alert means 100 may be an audio transducer 102 or may be a mechanical transducer to provide a detectable alarm which may be detected by the patient. When at least one ST segment shift determined by the microprocessor 84 is above a preset limit, which may be programmed into the microprocessor 84 from external to the apparatus 30 by the physician, the microprocessor then may be arranged to cause the alert means 100 to provide an alarm to the patient to inform the patient that the patient should consult his or her physician. Alternatively, if less sensitivity is desired, the microprocessor 84 may be programmed to activate the alarm only after a predetermined plurality of ST segment shifts, as for example, five ST segment shifts, have exceeded the preset limit. As a result, the apparatus 30 is capable of alerting the patient to a potential myocardial infarction episode before one occurs.

#### Claims

1. An apparatus (30) for assisting in the diagnosis of myocardial ischemia of a human heart, the apparatus being fully implantable beneath the skin of a patient and including at least one electrode (68) implantable beneath the skin of the patient and arranged for establishing electrical contact with the heart; a sensing stage (56) implantable beneath the skin of the patient and coupled to the at least one electrode for generating an electrogram representative of the activity of the heart at the at least one electrode, the electrogram including ST segments, a reader (58) implantable beneath the skin of the patient for converting the electrogram to digital data including ST segment digital data;

a memory (60) implantable beneath the skin of a patient for storing digital data;

a microprocessor (84) coupled to the reader and to the memory for causing only electrogram ST segment digital data to be stored in the memory; and

telemetry (62) implantable beneath the skin of a patient and coupled to the memory for transmitting the electrogram ST segment digital data responsive to an external command to a non-implantable external receiver.

2. The apparatus of claim 1 further characterized by a plurality of the electrodes (66, 68, 70) and the sensing stage generating an electrogram for each electrode.
3. The apparatus of claims 1 or 2 further characterized by the reader being an analog to digital converter (80).
4. The apparatus of claims 2 or 3 further character-

ized by the sensing stage including a plurality of sense amplifiers (72, 74, 76), each sense amplifier being coupled to a respective one of the electrodes.

5. The apparatus of claim 4 further characterized by a multiplexer (82) coupled to the sense amplifiers and an output coupled to the reader for coupling each of the sense amplifiers to the reader one at a time.
6. The apparatus of claims 1, 2, 3, 4, or 5 wherein the sensing stage, the reader, the memory, and the telemetry are enclosed within a common enclosure (64).
7. The apparatus of claims 1, 2, 3, 4, 5 or 6 further characterized by the microprocessor storing the electrogram ST segment digital data as ST segment voltage magnitudes in the memory (60).
8. The apparatus of claim 7 further characterized by the microprocessor determining the difference between ST segment voltages and a base line voltage and activating an alarm (100) when the absolute magnitude of at least one of the differences exceeds a limit.
9. The apparatus of claim 7 further characterized by the microprocessor determining the difference between ST segment voltages and the base line voltage and to cause an ST segment voltage magnitude to be stored in the memory only when the absolute magnitude of its corresponding difference exceeds a limit.
10. The apparatus of claim 9 further characterized by the microprocessor providing a time stamp for each ST segment voltage magnitude entered into the memory.

#### Patentansprüche

1. Vorrichtung (30) zur Unterstützung der Diagnose von Myocardischämie eines menschlichen Herzens, wobei die Vorrichtung vollständig unter die Haut eines Patienten implantierbar ist und zumindest eine Elektrode (68), die unter die Haut des Patienten implantierbar und dazu ausgestaltet ist, einen elektrischen Kontakt mit dem Herzen zu bewirken; eine Meßstufe (56), die unter die Haut des Patienten implantierbar und mit der zumindest einen Elektrode gekoppelt ist, um ein Elektrogramm zu erzeugen, das die Aktivität des Herzens an der zumindest einen Elektrode darstellt, wobei das Elektrogramm ST-Strecken enthält; eine Lese-einrichtung (58), die unter die Haut des Patienten implantierbar ist, um das Elektrogramm in digitale Daten zu konvertieren, die digitale ST-Streckendaten enthalten;

- einen Speicher (60), der unter die Haut eines Patienten implantierbar ist, um digitale Daten zu speichern;
- einen Mikroprozessor (84), der mit der Lese-  
einrichtung und mit dem Speicher gekoppelt ist, um zu bewirken, daß nur digitale ST-Streckendaten des Elektrogramms in dem Speicher gespeichert werden; und
- eine Fernübertragungseinrichtung (62) aufweist, die unter die Haut eines Patienten implantierbar ist und mit dem Speicher gekoppelt ist, um in Reaktion auf einen von außen kommenden Befehl die digitalen ST-Streckendaten des Elektrogramms zu einem nichtimplantierbaren externen Empfänger zu übertragen.
2. Vorrichtung nach Anspruch 1, weiterhin dadurch gekennzeichnet, daß eine Anzahl von Elektroden (66, 68, 70) vorgesehen ist, wobei durch die Meßstufe für jede Elektrode ein Elektrogramm erzeugt wird.
  3. Vorrichtung nach Anspruch 1 oder 2, weiterhin dadurch gekennzeichnet, daß die Leseeinrichtung ein Analog/Digital-Wandler (80) ist.
  4. Vorrichtung nach Anspruch 2 oder 3, weiterhin dadurch gekennzeichnet, daß die Meßstufe eine Anzahl von Meßverstärkern (72, 74, 76) aufweist, wobei jeder Meßverstärker mit einer der Elektroden gekoppelt ist.
  5. Vorrichtung nach Anspruch 4, weiterhin dadurch gekennzeichnet, daß ein Multiplexer (82) vorgesehen ist, der mit den Meßverstärkern gekoppelt ist und einen Ausgang hat, der mit der Leseeinrichtung gekoppelt ist, um zu einem Zeitpunkt jeweils einen der Meßverstärker mit der Leseeinrichtung zu koppeln.
  6. Vorrichtung nach Anspruch 1, 2, 3, 4 oder 5, wobei die Meßstufe, die Leseeinrichtung, der Speicher und die Fernübertragungseinrichtung in einem gemeinsamen Gehäuse (64) eingeschlossen sind.
  7. Vorrichtung nach Anspruch 1, 2, 3, 4, 5 oder 6, weiterhin dadurch gekennzeichnet, daß der Mikroprozessor die digitalen ST-Streckendaten des Elektrogramms als ST-Streckenspannungswerte in dem Speicher (60) speichert.
  8. Vorrichtung nach Anspruch 7, weiterhin dadurch gekennzeichnet, daß durch den Mikroprozessor die Differenzen zwischen den ST-Streckenspannungen und einer Basisspannung bestimmt werden und daß ein Alarmsignal (100) erzeugt wird, wenn der Absolutwert zumindest einer der Differenzen einen Grenzwert übersteigt.

9. Vorrichtung nach Anspruch 7, weiterhin dadurch gekennzeichnet, daß durch den Mikroprozessor die Differenz zwischen ST-Streckenspannungen und der Basisspannung bestimmt wird und daß ein ST-Streckenspannungswert nur dann im Speicher gespeichert wird, wenn der Absolutwert seiner zugehörigen Differenz einen Grenzwert übersteigt.
10. Vorrichtung nach Anspruch 9, weiterhin dadurch gekennzeichnet, daß durch den Mikroprozessor für jeden in dem Speicher gespeicherten ST-Streckenspannungswert eine Zeitmarkierung gesetzt wird.

#### Revendications

1. Appareil (30) destiné à faciliter le diagnostic de l'ischémie du myocarde d'un coeur humain, l'appareil étant totalement implantable sous la peau d'un patient et comprenant au moins une électrode (68) implantable sous la peau du patient et destinée à établir un contact électrique avec le coeur, un étage (56) de détection implantable sous la peau du patient et couplé à l'électrode au moins pour la création d'un électrogramme représentatif de l'activité du coeur au niveau de l'électrode au moins, l'électrogramme contenant des segments ST, un organe de lecture (58) implantable sous la peau du patient et destiné à transformer l'électrogramme en données numériques comprenant des données numériques de segment ST,  
  
une mémoire (60) implantable sous la peau du patient et destinée à mémoriser des données numériques,  
un microprocesseur (84) couplé à l'organe de lecture et à la mémoire destiné à provoquer la mémorisation dans la mémoire uniquement de données numériques de segment ST d'électrogramme, et  
un dispositif de télémetrie (62) implantable sous la peau du patient et couplé à la mémoire afin qu'il transmette les données numériques de segment ST d'électrogramme à la suite d'une commande externe vers un récepteur externe non implantable.
2. Appareil selon la revendication 1, caractérisé en outre par plusieurs électrodes (66, 68, 70), et en ce que l'étage de détection crée un électrogramme pour chaque électrode.
3. Appareil selon la revendication 1 ou 2, caractérisé en outre en ce que l'organe de lecture est un convertisseur analogique-numérique (80).
4. Appareil selon la revendication 2 ou 3, caractérisé en outre en ce que l'étage de détection comprend plusieurs amplificateurs de détection (72, 74, 76), chaque amplificateur étant couplé à une électrode

respective.

5. Appareil selon la revendication 4, caractérisé en outre par un multiplexeur (82) couplé aux amplificateurs de détection, ayant une sortie couplée à l'organe de lecture afin que chacun des amplificateurs de détection soit couplé à l'organe de lecture à son tour. 5
6. Appareil selon la revendication 1, 2, 3, 4 ou 5, dans lequel l'étage de détection, le détecteur, la mémoire et le dispositif de télémétrie sont enfermés dans une enceinte commune (64). 10
7. Appareil selon la revendication 1, 2, 3, 4, 5 ou 6, caractérisé en outre en ce que le microprocesseur conserve les données numériques de segment ST d'électrogramme sous forme d'amplitudes de tension de segment ST dans la mémoire (60). 15
8. Appareil selon la revendication 7, caractérisé en outre en ce que le microprocesseur détermine la différence entre les tensions de segment ST et une tension de ligne de référence et active une alarme (100) lorsque l'amplitude absolue de l'une au moins des différences dépasse une limite. 20 25
9. Appareil selon la revendication 7, caractérisé en outre en ce que le microprocesseur détermine la différence entre les tensions de segment ST et la tension de ligne de référence et provoque la mémorisation d'une amplitude de tension de segment ST dans la mémoire uniquement lorsque l'amplitude absolue de sa différence correspondante dépasse une limite. 30 35
10. Appareil selon la revendication 9, caractérisé en outre en ce que le microprocesseur donne une indication de temps pour chaque amplitude de tension de segment ST transmise dans la mémoire. 40

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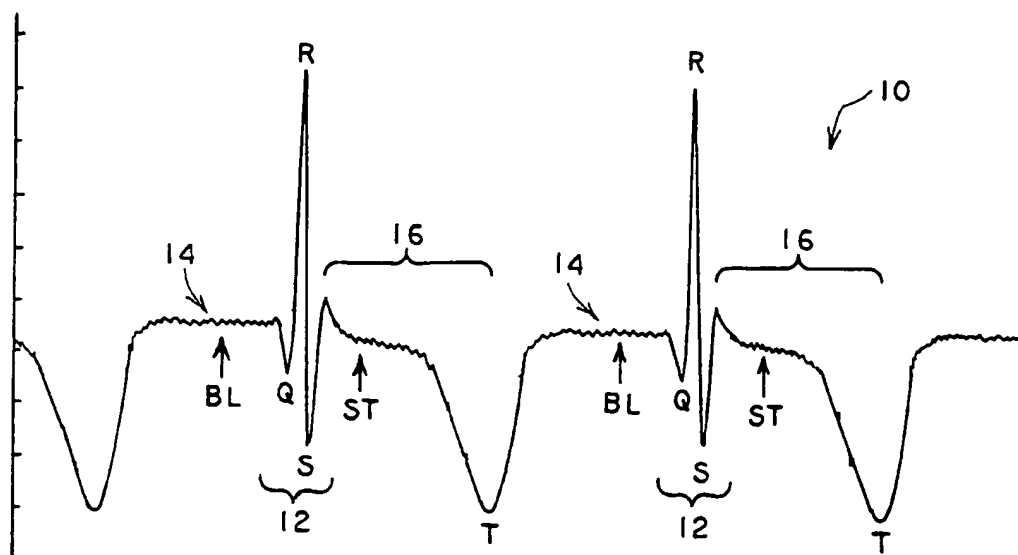


FIG. 1

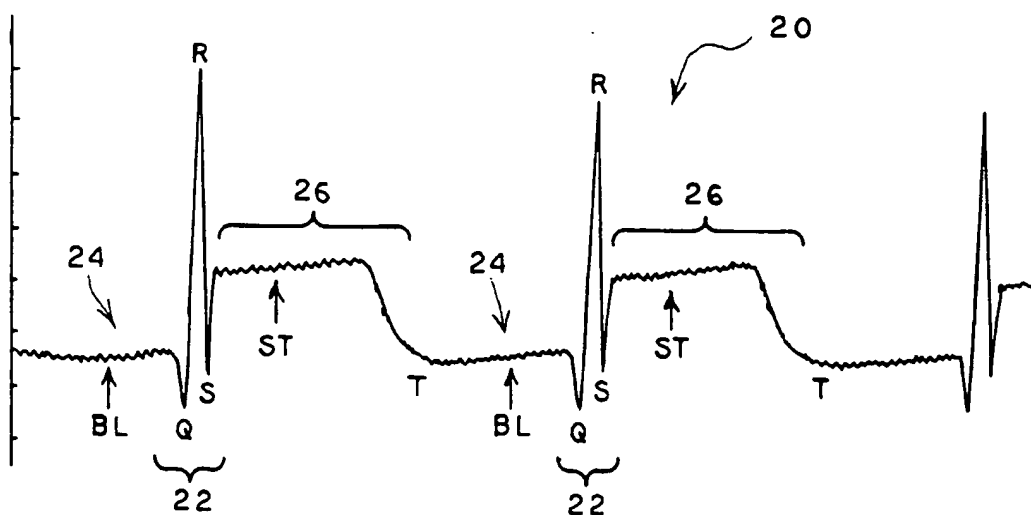


FIG. 2



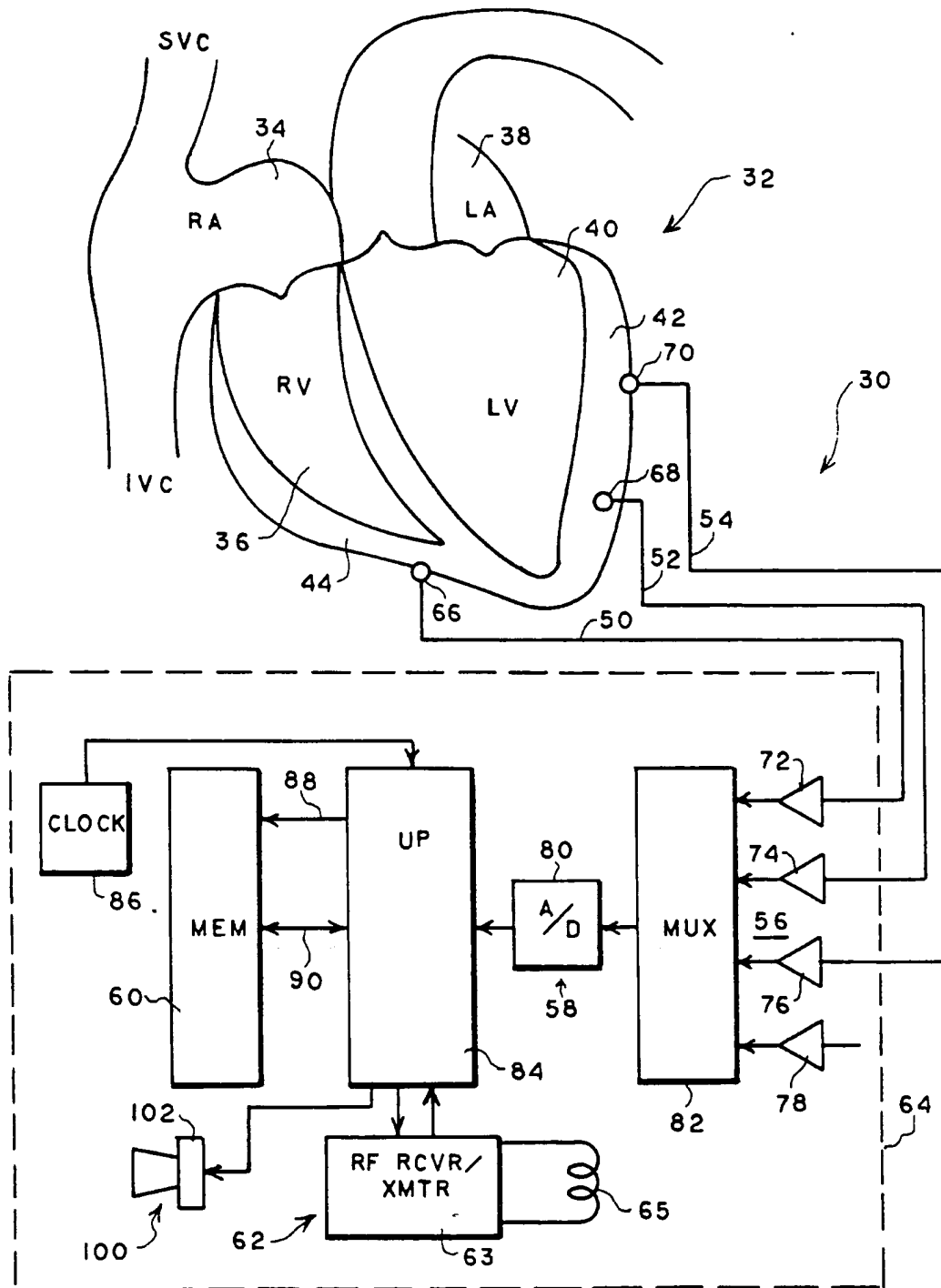


FIG. 3